



PHILIP MORRIS
PRODUCTS S.A.

MR0000075

June 8, 2017

Ms. Ann Simoneau
Director, Office of Compliance and Enforcement
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via ESG

**Re: Response to Office of Compliance and Enforcement Request for
MR0000059 IQOS system with Marlboro HeatSticks;
MR0000060 IQOS system with Marlboro Smooth Menthol HeatSticks; and
MR0000061 IQOS system with Marlboro Fresh Menthol HeatSticks**

Dear Ms. Simoneau,

Further to your Inspection Request letter dated May 25, 2017, please find herewith the requested information in [Appendix A](#) for the mentioned facilities.

We confirm that the inspection team will be able to observe the manufacturing and testing processes of the MRTPA products during the periods mentioned and that records related to the manufacturing, quality control, ex-batch release and stability testing are accessible and can be reviewed during the scheduled inspections.

This response contains confidential commercial and/or trade secret information. Protection of this information from public disclosure is hereby claimed under the applicable provisions of United States law. We request the agency to provide pre-disclosure notification and follow the procedures in 21 C.F.R. §20.61(e) before publicly disclosing any information contained in the response.

We remain available for any further information that is required.

Sincerely,

Malgorzata Wronowska, PhD
Director Regulatory and Scientific Affairs
Philip Morris Products S.A.

Jeffrey Walker, M.D.
US Agent for PMP S.A.
CEO, Teton Regulatory Sciences

cc: Matthew R. Holman, Ph.D.
Director, Office of Science
Center for Tobacco Products